Original Article

Perinatal Substance Abuse Intervention in Obstetric Clinics Decreases Adverse Neonatal Outcomes

Mary Anne Armstrong, MA
Veronica Gonzales Osejo, BS
Leslie Lieberman, MSW
Diane M. Carpenter, MPH
Philip M. Pantoja, MA
Gabriel J. Escobar, MD

OBJECTIVE:
To evaluate the effect of Early Start, a managed care organization's obstetric clinic-based perinatal substance abuse treatment program, on neonatal outcomes.

STUDY DESIGN:
Study subjects were 6774 female Kaiser Permanente members who delivered babies between July 1, 1995 and June 30, 1998 and were screened by completing prenatal substance abuse screening questionnaires and urine toxicology screening tests. Four groups were compared: substance abusers screened, assessed, and treated by Early Start ("SAT," $n = 782$); substance abusers screened and assessed by Early Start who had no follow-up treatment ("SA," $n = 348$); substance abusers who were only screened ("S," $n = 262$); and controls who screened negative ("C," $n = 5382$).

RESULTS:
Infants of SAT women had assisted ventilation rates (1.5%) similar to control infants (1.4%), but lower than the SA (4.0%, $p = 0.01$) and S groups (3.1%, $p = 0.12$). Similar patterns were found for low birth weight and preterm delivery.

CONCLUSION:
Improved neonatal outcomes were found among babies whose mothers received substance abuse treatment integrated with prenatal care. The babies of SAT women did as well as control infants on rates of assisted ventilation, low birth weight, and preterm delivery. They had lower rates of these three neonatal outcomes than infants of either SA or S women.
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INTRODUCTION

Substance abuse during pregnancy is a major problem in the US, with many adverse maternal, fetal, and neonatal effects.[1–6] National guidelines consider screening and referral for substance abuse to be essential components of prenatal care.[7] Moreover, *Healthy People 2010* explicitly states a national goal of increasing the proportion of pregnant women who achieve complete abstinence from alcohol to 94%, with 100% abstinence from illicit drugs.[8]

Although few dispute these goals, implementing them is difficult, particularly because public policies regarding screening and treatment for substance abuse are contradictory. In some states, screening has resulted in criminal prosecution of pregnant women.[7,9,10] Other states have adopted different approaches. For example, in November 2000, California voters approved Proposition 36, which strongly encourages treatment rather than incarceration for nonviolent illegal drug use.[11] Moreover, despite its presence in national guidelines, the existing literature provides limited information about treatment of pregnant women in managed care organizations and community settings. Most published reports focus on interventions that were implemented in research settings with primarily indigent women as subjects[12,13] and with small sample sizes, typically less than 150 women.[14,15]

The purpose of this study was to evaluate the relationship between maternal substance abuse intervention during pregnancy, as provided by a large, community clinic-based program, and subsequent neonatal outcomes. In 1990, the Kaiser Permanente Medical Care Program (KPMCP), Northern California Region, began an obstetric clinic-based perinatal substance abuse intervention program known as Early Start.[16] This program provides pregnant women with screening and early identification of substance abuse problems, early intervention, ongoing counseling, and case management by a licensed clinical therapist with expertise in substance abuse — the Early Start Specialist.

Kaiser Permanente Medical Care Program (M.A.A., V.G.O., D.M.C., G.J.E.), Division of Research, Perinatal Research Unit, Oakland, CA, USA; Kaiser Foundation Health Plan (L.L.), Patient Care Services, Oakland, CA, USA; Department of Pediatrics (G.J.E.), Kaiser Permanente Medical Center, Walnut Creek, CA, USA; and RAND (P.M.P.), Santa Monica, CA, USA.

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Address correspondence and reprint requests to Mary Anne Armstrong, MA, Kaiser Permanente, Division of Research, Perinatal Research Unit, 2000 Broadway, Oakland, CA 94611, USA.

MATERIALS AND METHODS

Study Design and Setting

This study was a retrospective cohort study. The setting was the KPMCP, Northern California Region, a group model managed care organization with integrated information systems. The study sites were the 10 KPMCP obstetric outpatient clinics (located in Fairfield, Hayward, Oakland, Pleasanton, Richmond, San Francisco, South Sacramento, Vacaville, Vallejo, and Walnut Creek) where the Early Start Program was in operation during the study period and the 10 Northern California Kaiser Foundation hospitals with labor and delivery facilities that serve those clinics.

Potential Early Start Program clients were identified based on (1) responses to the self-administered prenatal substance abuse screening questionnaire, which is completed at the first prenatal appointment, using a standardized protocol; (2) clinician referral; (3) self-referral; and/or (4) positive urine toxicology screen results, which are reviewed by a clinician at prenatal care appointments. Women who are identified as having some risk for alcohol, tobacco, or other drug use during pregnancy are then immediately referred to the Early Start Specialist who conducts an in-depth psychosocial assessment with the patient, which concludes with a diagnosis based on DSM-4 criteria and a follow-up care plan. Those women who are assessed as chemically dependent, substance-abusing, problem drinkers, or problem drug users and are felt to be at risk for substance use problems during pregnancy are seen for counseling with the Early Start Specialist at subsequent prenatal visits. A variety of counseling techniques are used, including motivational therapy, cognitive/behavioral therapy, and psychodynamic therapy. Early Start clients are referred to other intervention programs as needed. It is important to note that the screening and treatment process does not always result in all substance-abusing patients entering care. In addition to some patients choosing not to come back for return appointments, scheduling difficulties can occur and may lead to some women not receiving Early Start intervention. We have described the Early Start Program, including the screening questionnaire, in greater detail elsewhere.[16]

The Early Start Program was designed to diagnose all levels of substance abuse problems. Women diagnosed as substance abusers, problem drinkers, or problem drug users are scheduled for Early Start appointments linked with their prenatal appointments. Women diagnosed as chemically dependent may also be referred to chemical dependency treatment programs. The unique feature of the Early Start Program is that the Early Start Specialist is located in the prenatal clinic, where she is an integral part of the prenatal care team. This promotes easy access to services and enhances patient compliance. Like many innovative projects in complex organizations, implementation of the program did not occur in all sites immediately, and the program has had (and continues to experience) logistic difficulties as it expands to new sites.[16] Nonetheless, in 2001, Early Start screened almost 23,000 women in 18 of the KPMCP's 33 outpatient prenatal care clinics. In those centers where it operates, Early Start screening and voluntary urine toxicology screening upon entry to prenatal care are the standards of care.

Study Subjects and Database Development

The study cohort included 6774 female Kaiser Permanente members and their babies who were delivered between July 1, 1995 and June 30, 1998. Study eligibility required that the mother has completed an Early Start Prenatal Screening Questionnaire during the pregnancy. Only the first pregnancy for each woman which resulted in a live birth was included in the cohort. Multiple gestations were excluded.

The KPMCP's information systems employ a common medical record number and a clinical data repository, permitting multiple database linkages across facilities and comprehensive follow-up on a population basis, as we have described elsewhere.[17–19] These systems also have several security components to ensure that access to confidential information (e.g., urine toxicology screen results) is limited to authorized individuals. We linked several KPMCP data sources to develop a comprehensive database for analysis. KPMCP databases were scanned to identify pregnant women who delivered during the study period, to gather their outpatient and inpatient course, and to record their outcomes. Neonatal outcomes were obtained from a research database, the Neonatal Minimum Data Set.[18,20] Our data abstraction and electronic linkage methods have been described elsewhere.[17–23]

The Early Start Program maintains three databases: (1) responses to the Early Start Prenatal Substance Abuse Screening Questionnaire, (2) Early Start patient assessment results as recorded by the Early Start Specialist, and (3) Early Start follow-up visit summary data. These databases were available electronically and were included in the analysis database.

The Early Start Program routinely uses urine toxicology screening tests as a measure of substance abuse. All pregnant patients are asked to consent in writing to have urine toxicology testing performed at the first prenatal visit (referred to as the "universal test") and during pregnancy. These tests screen for nine substances of abuse: alcohol, amphetamines, barbiturates, benzodiazepines, cocaine, methamphetamines, opiates, PCP, and THC (marijuana). The test results are stored electronically and are added to the database.[16]

Study Groups

We defined four study groups. Group 1, "screened, assessed, and treated" (SAT), ($n = 782$) consisted of women who were screened and assessed by the Early Start Program and diagnosed as chemically dependent or substance-abusing by an Early Start Specialist and had at least one follow-up Early Start appointment. Group 2, "screened and assessed" (SA) ($n = 348$), consisted of women assessed and diagnosed as chemically dependent or substance-abusing by an Early Start Specialist but who, for a variety of reasons, did not have any subsequent Early Start follow-up appointments. Group 3, "screened only" (S) ($n = 262$), consisted of pregnant women who

were identified as substance abusers based on screening but, for a variety of reasons, were never assessed or treated by the Early Start Program. Women in Group 3 had a positive universal toxicology screening test with either a positive screening questionnaire ($n=108$) or a negative screening questionnaire ($n=154$). Group 4, ''controls'' (C) ($n=5382$), was composed of women with no evidence of substance abuse during pregnancy, defined as a negative screening questionnaire and a negative universal toxicology test.

This study was approved by the KPMCP Institutional Review Board for the Protection of Human Subjects.

Statistical Analysis

Four neonatal outcomes were analyzed: neonatal assisted ventilation, low birth weight, preterm delivery, and Neonatal Intensive Care Unit (NICU) admission. Assisted ventilation was defined as either intermittent mandatory ventilation or nasal continuous airway pressure, both of which require additional nursing as well as respiratory technician staffing. A baby was considered premature if born at <37 completed weeks of gestation. Low birth weight was defined as <2500 g. The 24 neonatal deaths that occurred during the birth hospitalization were analyzed separately and were deleted from the final analysis due to small numbers.

We employed χ-squared analyses to compare the four study groups on demographic variables, substance abuse risk factors, and the rates of the four neonatal outcome variables. Separate logistic regression models were used to estimate the odds ratios for each outcome, comparing each of the three substance-abusing groups to the control group. Models were controlled for maternal age, ethnicity, and the number of prenatal visits during the pregnancy (adjusted for the number of weeks of gestation at delivery).

RESULTS

Table 1 provides demographic comparisons of maternal and neonatal factors for the four study groups. The SAT and SA groups were similar on all of the maternal demographic variables and there were no significant differences between the two groups (all p values ≥ 0.02). They were younger, unmarried, less educated, had less income, and were more likely to be of black or white race than the controls. The S group was similar to the SAT and SA groups in terms of marital status, education, and income, but they were less likely to be younger than 19 years old (SAT versus S: $p=0.001$; SA versus S: $p=0.009$) and more likely to be black (SAT versus S: $p=0.003$; SA versus S: $p=0.001$).

The percentage of women who began prenatal care late, defined as first prenatal visit after 13 weeks of gestational age, was significantly higher in all three substance-abusing groups compared to the controls (all p values <0.0001). The rate for the SAT

Table 1 Demographic Characteristics by Study Group

Characteristic	Group			
	Screened, assessed, and treated (SAT) ($n=782$)	Screened and assessed (SA) ($n=348$)	Screened only (S) ($n=262$)	Controls (C) ($n=5382$)
Maternal age (%)				
<19 years	20.1	17.0	9.5	5.6
>35 years	7.2	10.1	8.0	11.2
Maternal race (%)				
White	40.4	47.4	31.3	31.3
Black	30.7	28.2	40.8	15.8
Hispanic	12.8	8.1	13.7	20.3
Asian	3.6	6.0	5.7	23.5
Other	12.4	10.3	8.4	8.8
Marital status (% married)	41.4	46.8	51.5	74.6
Education (% $\leq$ high school)	53.3	50.9	46.6	31.0
Annual income (% <US$25,000)	52.4	45.7	48.1	27.4
Gestational age at delivery (%)				
<33 weeks	1.0	2.3	1.2	0.8
33–36 weeks	5.4	6.6	9.2	5.0
>36 weeks	93.4	91.1	89.7	94.2
Mean birth weight in grams (SD)	3379 (560)	3365 (626)	3310 (581)	3436 (548)
Median newborn length of hospital stay in hours (interquartile range)	37 (27–56)	38 (28–61)	40 (26–62)	34 (25–53)
Late (>13 weeks) to prenatal care (%)	26.2	34.8	31.3	18.4
Median amount of prenatal care* (interquartile range)	0.32 (0.25–0.38)	0.28 (0.22–0.35)	0.28 (0.22–0.34)	0.28 (0.24–0.34)

*Number of prenatal visits during pregnancy divided by the number of weeks of gestation at delivery.

women was significantly lower than the rate for the SA group ($p = 0.003$). The SAT group had a significantly higher median amount of prenatal care than the SA, S, and control groups (all p values < 0.0001).

Table 2 provides comparisons of the four groups on substance use risk factors, based on responses to the Early Start screening questionnaire and toxicology screening results. There were no statistical differences among the three substance-abusing groups on rates of use during pregnancy for the six substances reported on the screening questionnaire. However, before pregnancy, SAT and SA women were more likely than the S women to use alcohol and marijuana at least weekly. All three substance-abusing groups had

Table 2 Substance Use Risk Factors by Study Group

Risk factor	Group % in each group			
	Screened, assessed, and treated (SAT)	Screened and assessed (SA)	Screened only (S)	Controls (C)
Screening questionnaire data				
Used weekly or daily since pregnancy				
Alcohol	6.7	10.3	5.7	0.0
Cocaine	0.8	0.9	0.4	0.0
Heroin	0.8	0.3	0.0	0.0
Methamphetamines	2.6	1.4	1.2	0.0
Pain medications	1.9	2.0	2.3	0.0
THC	13.2	8.9	6.9	0.0
Used weekly or daily before pregnancy				
Alcohol	28.0	28.7	18.7	5.9
Cocaine	1.3	2.3	0.4	0.0
Heroin	1.4	0.3	0.0	0.0
Methamphetamines	8.8	5.5	2.7	0.0
Pain medications	4.1	3.5	3.8	1.4
THC	31.1	22.4	14.5	0.0
Smoked cigarettes during pregnancy				
Daily	25.5	29.0	17.2	1.2
Never	56.5	55.0	69.9	95.9
Risk questions				
Annoyed by criticism of substance use	12.8	8.6	3.1	0.0
Ever felt ought to cut down	32.2	24.4	13.0	0.0
Ever used more than you planned	27.9	22.4	9.9	0.0
Feel you may have trouble staying off	17.1	17.2	9.5	0.0
Family history	49.9	46.6	29.8	17.5
>3 drinks to feel high	10.4	9.8	5.0	0.0
Yes to ≥ 2 risk questions	24.2	17.8	6.9	0.0
Toxicology screen data				
Ever positive during pregnancy	67.7	55.2	100.0	0.0
Alcohol	8.4	6.3	27.9	0.0
Barbiturates	1.9	1.7	5.0	0.0
Benzodiazepines	0.6	0.6	1.2	0.0
Cocaine	5.0	4.0	3.1	0.0
Methamphetamines/amphetamines	8.6	10.6	13.4	0.0
Opiates	7.4	4.6	11.8	0.0
PCP	0.1	0.0	0.4	0.0
THC	55.5	42.0	59.5	0.0
Two or more substances	16.9	12.6	18.7	0.0

Table 3 Unadjusted Rates of Assisted Ventilation, Low Birth Weight, Preterm Delivery, and NICU Admission According to Study Group

Outcome	Group unadjusted rate (%) (significant p values)			
	Screened, assessed, and treated (SAT)	Screened and assessed (SA)	Screened only (S)	Controls (C)
Assisted ventilation	1.5 (0.010 vs SA)	4.0 (0.001 vs C)	3.1 (0.024 vs C)	1.4
Birth weight <2500 g	4.7 (0.028 vs SA; 0.015 vs S)	8.1 (0.001 vs C)	8.8 (0.001 vs C)	3.7
Gestational age <37 weeks	6.4 (0.037 vs S)	8.9 (0.015 vs C)	10.3 (0.002 vs C)	5.7
NICU admission	13.6 (0.014 vs SA; 0.001 vs C)	19.3 (0.001 vs C)	15.3 (0.001 vs C)	7.6

higher rates of daily smoking than controls. Additionally, SAT and SA women had higher daily smoking rates than the S group.

Six questionnaire items were chosen as indicative of substance abuse risk. For each item, the SAT and SA groups had higher rates than the S group ($p<0.008$ for each comparison) (Table 2). They also had higher proportions of women responding ''yes'' to two or more of the six questions.

SAT women were significantly more likely than the SA group to ever have a positive toxicology screening test during pregnancy ($p=0.001$). Comparisons of positive toxicology screening rates by type of drug found that: (1) the SAT and SA women were less likely than the S group to ever have positive toxicology screens for alcohol ($p=0.001$), and (2) the SA group was less likely than either the SAT or S group to ever be positive for marijuana ($p=0.001$).

The unadjusted rates of the four outcomes by study group are shown in Table 3. We found similar patterns in the results for assisted ventilation, low birth weight, and preterm delivery. The SAT group had rates similar to the controls (all p values >0.17) for these three outcomes, whereas in all comparisons, the SA and S groups had significantly higher rates than the controls for these three outcomes. The SAT group had lower rates than the SA group and the S group for assisted ventilation, low birth weight, and preterm delivery. NICU admission results were somewhat different, with all three substance-abusing groups having higher rates than the controls.

Of the 24 neonatal deaths in the study cohort, none occurred in the SAT group (0.0%), 2 in the SA group (0.57%), 2 in the S group (0.76%), and 20 in the control group (0.37%). Although the S group has the highest rate, no statistical differences were found among the groups.

We conducted multivariate logistic regression analyses on each of the four outcomes. The final models included maternal age, ethnicity, and the number of prenatal visits during the pregnancy adjusted for the number of weeks of gestation at delivery; late to prenatal care and other potential risk factors were not significant confounders and were omitted from the final models. The results were similar to those of the bivariate analysis (Table 4). The odds ratios comparing the SAT group to the controls for assisted ventilation, low birth weight, and preterm delivery were not significantly elevated. However, the odds ratios for both the SA and S groups compared to the controls were elevated. The results for NICU admission showed the same pattern as in the unadjusted analysis: the odds ratios for all three substance-abusing groups compared to the controls were significantly elevated.

DISCUSSION

This study presents information on substance abuse treatment and screening in a population that is not usually described in the literature: pregnant women in a managed care organization treated outside the research setting. We have found that providing such treatment has a beneficial effect on newborns in terms of assisted ventilation, low birth weight, and premature delivery. We feel that NICU admission was not impacted because it is not always a sensitive measure of neonatal morbidity. We and others have documented that many NICU admissions are for highly discretionary reasons, such as ''admitted for observation'' or ''rule out sepsis,'' that are subject to considerable practice variation.[18,24–26] Given that different drugs affect multiple organ systems in both mother and fetus,[6,27] and because women who use drugs of abuse may also have other

Table 4 Adjusted Odds Ratios for Assisted Ventilation, Low Birth Weight, Preterm Delivery, and NICU Admission According to Study Group

Outcome	Group odds ratios* (95% CI; p value versus C)			
	Screened, assessed, and treated (SAT)	Screened and assessed (SA)	Screened only (S)	Controls (C) (reference)
Assisted ventilation	1.2 (0.6–2.3; 0.56)	3.1 (1.7–5.7; 0.0003)	2.0 (0.9–4.3; 0.07)	1.0
Birth weight <2500 g	1.5 (1.0–2.1; 0.05)	2.4 (1.6–3.7; 0.0001)	2.5 (1.6–3.9; 0.0001)	1.0
Gestational age <37 weeks	1.3 (0.9–1.8; 0.11)	1.6 (1.1–2.4; 0.02)	1.7 (1.2–2.8; 0.006)	1.0
NICU admission	2.2 (1.7–2.8; 0.0001)	3.2 (2.5–4.5; 0.0001)	2.1 (1.5–3.1; 0.0001)	1.0

*Estimated from logistic regressions coefficients, controlled for maternal age, ethnicity, and amount of prenatal care.

problems,[27] it is not possible for us to postulate what specific biological mechanisms account for the benefits we have observed and described. However, we can speculate that the benefits of Early Start are likely to stem from two factors. The first is that the program does, in fact, decrease or remove the exposure (i.e., drugs with harmful effects). The second is that the Early Start Program may also affect patient health and the process of care through indirect means. Improved outcomes may be partly the result of the social support it provides pregnant women. Contact with the Early Start Specialist may also lead to heightened alertness on the part of clinicians, leading to earlier detection of problems prior to delivery. However, full elucidation of these effects is outside the scope of this paper.

Our study has several important limitations. It is important to note that we are reporting on an evaluation of a program that was designed to help patients, not on a research project. There are inherent limitations to evaluating nonrandomized community-based interventions that are gradually implemented, such as case ascertainment, self-selection, and severity of substance abuse (degree of exposure). It is difficult to ensure 100% ascertainment of drug-using patients, even if one employs urine toxicology screens,[28,29] and identifying alcohol abusers is particularly problematic.[28,29] Do the women who see an Early Start Specialist during their pregnancy have less serious substance abuse problems than women who abuse substances but who elect not to participate in Early Start? It is evident that the success of any given intervention can be strongly affected by the type and degree of substance abuse (severity of illness). Certain intervention types may have an impact on substance-abusing women with mild problems but not on those with severe ones.

Given the data sources available to us, we cannot completely overcome the above limitations, but our methods suggest that we have been able to minimize the impact. We used a combination of strategies to identify substance-abusing women: a screening questionnaire, which includes modified CAGE and TWEAK questions; universal urine toxicology testing; and clinician referral. To address the issue of self-selection and severity of illness, we examined the three groups of substance-abusing women in terms of available risk factors and variables indicative of severity of substance abuse. We found that the SAT women had similar or higher rates on these factors than the S group (Table 2), indicating that they did not have less serious problems. Case management is an integral part of the Early Start model. The Early Start Specialists see women with all levels of severity of substance abuse. Women with very severe problems are referred to more intensive substance abuse treatment programs in the psychiatry department, but their case is still managed by the Early Start Specialist, who continues to see the woman as often as possible.

Our results must also be considered from a national health policy perspective. It is clear that, purely on ethical grounds, the medical profession and our society must attempt different, nonpunitive solutions to the problem of substance abuse. Programs such as Early Start are important because they address this problem ''in the mainstream,'' in a managed care organization. The four outcomes we have reported on — use of assisted ventilation, low birth weight, prematurity, and admission to the NICU — are associated with increased mortality,[30–33] morbidity,[23,34–38] and costs.[39–42] It is important to study and demonstrate how an intervention integrated with prenatal care can be associated with tangible short-term improvements to a managed care organization. At the same time, our study documents that, even with programs such as Early Start in place, some women may not receive optimum treatment. For example, one reason we have been able to identify is that the Early Start Specialist may have trouble coordinating follow-up visits with regularly scheduled prenatal visits. This suggests that community-based substance abuse intervention programs need to analyze their caseload from standpoints other than merely ensuring initial access — a problem also affecting prenatal care that is beginning to get more detailed attention.[43]

An important subgroup of the pregnant substance-abusing population is women who deny substance use on their screening questionnaire, have a positive universal toxicology screening test, but are never seen by Early Start. These women are referred but are never assessed or treated by an Early Start Specialist for a variety of reasons, including patient refusal to take advantage of the program and access problems (Early Start Specialist availability, triage of patients, limited access to care due to lack of transportation, childcare, and so forth). In preliminary analyses, the babies of these women had much higher assisted ventilation rates (6.2%) than the babies of SAT women (1.5%). This group merits special attention and in-depth study.

In conclusion, improved neonatal outcomes were found among babies whose mothers received substance abuse treatment integrated with prenatal care, as provided by the Early Start Program. In particular, infants of substance-abusing women who were screened, assessed, and treated during pregnancy did as well as control infants on rates of assisted ventilation, low birth weight, and preterm delivery. These infants had lower rates of the three outcomes than infants of substance abusers who were screened and assessed but not treated by Early Start as well as those who were screened only with no Early Start Specialist contact.

Our study highlights the need to address the improvement of perinatal outcomes in nonacademic settings. It also shows how an alliance between clinicians and mental health professionals can be implemented. The most important implication for clinical practice in obstetrics is that close integration of substance abuse treatment with regular prenatal care is a viable strategy.

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